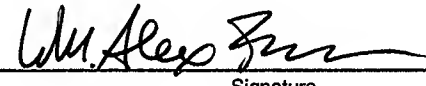


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PTO/SB/33 (07-09)

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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) 076775-011002	
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	First Named Inventor Kenneth A. Gall		
	Art Unit 3733	Examiner Merene, Jan Christopher	
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p>			
I am the		 Signature	
<input type="checkbox"/> applicant/inventor.		Wm. Alex Furman Typed or printed name	
<input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)			
<input checked="" type="checkbox"/> attorney or agent of record. Registration number 61,313		(303) 685-7417 Telephone number	
<input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____		12/2/10 Date	
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.			
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:

Gall et al.

Serial No.: 10/598,080

Filed: August 17, 2006

Confirmation No.: 9897

Atty. File No.: 076775.011002

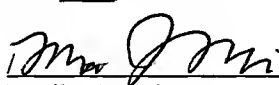
For: "A GRAFT FIXATION DEVICE AND  
METHOD"

) Group Art Unit: 3733

) Examiner: Merene, Jan Christopher

) **REMARKS ACCOMPANYING PRE-**  
) **APPEAL BRIEF REQUEST FOR**  
) **REVIEW**

) It is hereby certified that this correspondence is  
) being transmitted to the United States Patent and  
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) Signed:   
) Name: Marilyn Morris

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

These remarks accompany the Notice of Appeal and corresponding Pre-Appeal Brief Request for Review being filed contemporaneously herewith. In view of the following remarks, reevaluation and reconsideration of the application is requested.

**I. Introduction**

The pending claims are directed to a surgical method, the claims requiring (among other things):

- positioning the retention device in the recess while the shape memory polymer is in the temporary pre-implantation shape such that the retention device contacts the cable member and the bone; (the "positioning step") and
- causing the shape memory polymer to change its shape through the shape memory effect from the temporary pre-implantation shape toward an unconstrained shape of the shape memory polymer, thereby fixing the cable member to the bone with the retention device (the "causing step").

In the Final Office Action, the Examiner rejected the sole independent claim 46 as being obvious over, alternatively, U.S. Patent Publication No. 2002/0165547 to Dovesi

("Dovesi") and U.S. Patent No. 5,505,735 to Li ("Li"), in view of a published article by Lendlein et al. entitled "*Biodegradable, Elastic Shape-Memory Polymers for Potential Biomedical Applications*" ("Lendlein") as shown in Applicant's IDS of July 29, 2010.

Applicant submits that the rejections in the Final Office Action are without merit and, reserving the right to set forth other reasons on appeal, presents the following deficiencies in this Request. First, the Examiner's rejections of independent claim 46 are incomplete and improper, because the Examiner completely fails to address the positioning step and an element of the causing step, each of which were specifically added in Applicant's amendment to claim 46 filed July 22, 2010. Second, the Examiner relies on improper combinations of Dovesi with Lendlein and Li with Lendlein in supporting the incomplete obviousness rejections.

Applicant hereby requests that a Pre-Appeal Brief Review be performed as requested in the attached USPTO form SB/33.

## **II. The Examiner has failed to address all claim limitations in his rejection.**

The Final Office Action does not address limitations added in the most recent response resulting in an improper rejection under Section 103(a). MPEP § 2143.03. In the most recent response, filed July 22, 2010, Applicant amended the sole independent claim 46 as follows:

46. (Currently Amended) A method comprising:
- inserting a cable member into a recess in a bone;
  - inserting a retention device containing a shape memory polymer into the recess while the shape memory polymer is in a temporary pre-implantation shape due to a shape memory effect of the shape memory polymer; the retention device containing a shape memory material; and
  - positioning the retention device in the recess while the shape memory polymer is in the temporary pre-implantation shape such that the retention device contacts the cable member and the bone; and
  - causing activating the shape memory material polymer to change its shape through the shape memory effect from the temporary pre-implantation shape toward an unconstrained shape of the shape memory polymer, thereby fixing the cable member to the bone with the retention device.

However, in the Final Office Action, the Examiner simply repeats the rejections of the original version of claim 46. The Examiner then incompletely recites the amendments

made to claim 46, and then attempts to explain how the incompletely-recited deficiencies of Dovesi and Li are met by Lendlein in the following passage:

**Dovesi discloses the use of a shape memory material but does not disclose the retention device containing a shape memory polymer such that is inserted in a temporary pre-implantation shape and causing the polymer to change shape after implantation.**

**However, Lendlein discloses that shape memory polymers allow for implants to be placed through small incisions (see introduction on page 1673), wherein shape memory polymers possess the ability to memorize permanent shape that can substantially differ from their initial temporary shape, wherein bulkier devices can be introduced into the body in a compressed temporary shape (see last paragraph at the end of page 1673 continuing to the top paragraph of page 1674), wherein the shape memory polymer can be activated by heating (see page 1674, 2nd and 3<sup>rd</sup> paragraphs starting with "The thermally induced shape memory effect ...").**

Even taking the Examiner's explanation as facially valid, the above rejection does not address several important amendments that had been made to claim 46: (1) the entire "positioning step" remains unaddressed; and (2) the "thereby fixing the cable member to the bone with the retention device" element remains unaddressed.

Therefore, the rejections of claim 46 are incomplete and improper, and Applicant requests the rejections be withdrawn.

### **III. The Examiner has improperly combined Lendlein with Dovesi and with Li.**

The Examiner improperly combines Lendlein both with Dovesi and with Li because (1) the combined references teach away from each other and (2) the combination of either Dovesi or Li with Lendlein would render the Dovesi and Li devices inoperable for their intended purpose of fixing a tendon to bone. MPEP §§ 2143.01(V), 2145(X)(D). The Examiner must consider the nature of the teaching of the prior art because it is highly relevant to whether the combination of references is proper. MPEP §§ 2141.02, 2145(X)(D)(1). Here, Lendlein teaches away from combination with Dovesi and from combination with Li and any combination would be inoperable, resulting in an improper combination of references. MPEP §§ 2143.01(V), 2145(X)(D)(2).

**1. Lendlein teaches away from both Li and Dovesi.**

Li teaches fixation to bone using the pseudo-elastic properties of shape memory alloys, whereas Dovesi merely teaches that “[t]he device can be made of metal (titanium or steel) or of composite, absorbable or shape memory-materials.” (Dovesi Col. 3, ll. 38-39.) By contrast, Lendlein teaches the use of shape memory polymers for their superior compliance and therefore their superior suitability for use with soft tissues:

**the third cycle. Ni-Ti alloys show stresses in the range of 200 to 400 MPa during shape-memory transition, whereas the shape-memory thermoplastics produce stresses in the range between 1 and 3 MPa, depending on the hard segment content (23). The lower value for shape-memory polymers resembles the mechanical stresses in soft tissue (24).**

(Lendlein p. 1675.)

Lendlein further emphasizes the use of shape memory polymers for low force environments, such as sutures in arthroscopic surgery, through experimental results of a 1.6N tension on the suture, compared to 831.9N as the average pull-out tensile strength of a bone fixation system of Applicant’s disclosure. (See Applicant’s Fig. 20a.)

Therefore, the Examiner’s combinations of Lendlein with Dovesi and Lendlein with Li do not consider the entirety of the references or the significant aspects teaching away from their combination and the combinations are therefore improper. MPEP §§ 2141.02, 2145(X)(D).

**2. A combination of Lendlein and Dovesi or Li would not function as intended.**

The Examiner’s combination of Dovesi and Lendlein results in an incomplete and inoperable device. Again, Dovesi’s entire disclosure on the subject of shape memory materials consists of “[t]he device can be made of metal (titanium or steel) or of composite, absorbable or shape memory-materials.” (Col. 3, ll. 38-39.) Dovesi does not teach or suggest how using shape memory materials, such as Lendlein’s polymers, would differ from using common metals such as titanium or steel.

The Examiner’s combination of Li and Lendlein results in an incomplete and inoperable device. If a device substituted Li’s shape memory alloy with Lendlein’s shape memory polymer as the Examiner suggests, then Li’s anchoring barbs (36) would not function for their intended purpose of fixing tendon to bone. Li teaches a device using 8 or

12 anchoring barbs (36) with a diameter of 0.03 inches (0.762 mm) or an area of 0.000707 inches<sup>2</sup> (0.456 mm<sup>2</sup>) to be fixed within a bone tunnel. If one of Li's devices were created using the shape memory polymer teachings of Lendlein, the barbs would create only a maximum of 1.37 N of force per barb (3 MPa x 0.456 mm<sup>2</sup>/1,000,000) or a total of 16.4 N of force on the bone tunnel among all 12 barbs. Simply put, the 16.4 N of force generated by a combination of Li's teachings with Lendlein's would create an inoperable device for fixing tendon to bone, because it would only provide roughly 2% of the forces required by the fixation devices disclosed and claimed by Applicant.

Therefore, the Examiner's combinations of Lendlein with Dovesi and with Li would each lead to a device that would be non-functional and otherwise unsatisfactory for its intended purpose and the combinations are therefore improper. MPEP § 2143.01(V).

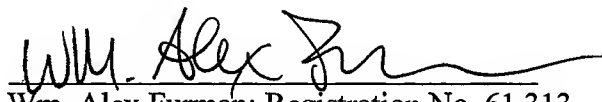
#### **IV. Conclusion**

In light of the above remarks, it is respectfully submitted that the presently pending claims are patentable over both Dovesi in view of Lendlein and Li in view of Lendlein. Reevaluation and reconsideration of the application is requested.

Respectfully submitted,

GREENBERG TRAURIG, LLP

Date: 12/2/10

  
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